

JUL 9 2003

K031199

510(k) Summary

Date prepared: March 7, 2003

Submitter: ZEVEX, Inc.
4314 ZEVEX Park Lane
Salt Lake City, UT 84123

Contact person: Sean M. Curry
16787 Bernardo Center Drive, Suite A-1
San Diego, CA 92128

Phone number: (858) 675-8200

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Proprietary name: EnteraLite® Infinity™ Enteral Feeding Pump

Common name: Infusion pump, Enteral, External

Classification: Class II

Product Code: 80LZH, 880.5725

Substantial equivalence claimed to:

K954735 – EnteraLite Enteral Feeding Pump - ZEVEX, Inc.

Description:

The EnteraLite® Infinity™ Enteral Feeding Pump as referred to as Infinity™ with disposable set is a small, lightweight pump used to dispense liquid nutrients at a user controlled rate to patients. The device may be used in the hospital or at home by bed-ridden or ambulatory patients. The device is also designed for use with pediatric patients.

The device is a software controlled, variable flow rate, peristaltic pump. It operates up to 24 hours (at a nominal flow rate of 125 ml/hr) from internal rechargeable batteries. The batteries are recharged by a wall mounted charger that plugs into a standard 100 to 240 volt alternating current wall socket. The charger is available in various input voltage and plug configurations to accommodate international requirements. The charger converts line voltage to a safe low voltage of 5 volts DC that is supplied from the charger to the pump. A "fuel gauge" type indicator on the pump's LCD display continuously shows the state of battery charge.

The pump motor runs at a single speed and is turned on and off at programmed intervals to obtain the desired flow rate. The motor drive circuit is controlled by a microcontroller that allows the motor to pause longer at lower flow rates with correspondingly shorter pauses at higher flow rates. The software embodied within the microcontroller is extensively validated and verified as part of the design process.

The pump includes several safety features. An air-in-line sensor rapidly detects whenever nutrient flow is interrupted and alerts the user with both a visual and audible alarm. Two pressure sensors detect occlusions both on the nutrient bag (distal) side and the patient (proximal) side of the pump. The user is alerted to proximal or distal occlusions by both visual and audible alarms.

The disposable tubing set consists of a bag, or spike for nutrient bag, DEHP free PVC connecting tubing, an integral cassette with a silicone pumping segment, and an enteral adapter. The set also contains a patented anti-free flow device within the cassette, a version of which is used in the stationary pumps manufactured by ZEVEX, which prevents free flow of fluids if the tubing set is inadvertently or purposely removed from the pump.

A backpack (convertible to a waistpack) is available for use under ambulatory conditions. The pump may be operated in any orientation.

Intended use:

The EnteraLite[®] Infinity[™] Enteral Feeding Pump is a rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.

Summary of technological characteristics:

The EnteraLite[®] Infinity[™] Enteral Feeding Pump is the next generation of the predicate device EnteraLite Enteral Feeding Pump by ZEVEX, Inc. This is essentially the same pump except that the EnteraLite[®] Infinity[™] Enteral Feeding Pump uses optical sensors for the pressure detection and air in line detection.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Zevex International, Incorporated
C/O Mr. Sean Curry
Certified Software Solutions, Incorporated
16787 Bernardo Center Drive, Suite A-1
San Diego, California 92128

Re: K031199

Trade/Device Name: EnteraLite® Infinity™ Enteral Feeding Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: April 9, 2003
Received: April 18, 2003

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", with a stylized, cursive script.

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K031199

Device Name: EnteraLite® Infinity™ Enteral Feeding Pump

Indications for Use:

The EnteraLite® Infinity™ Enteral Feeding Pump is a rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Patricia C. [Signature] _____
Special Agent in Charge, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031199

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____